



1645
PH9

PTO/SB/21 (08-00)

Approved for use through 10/31/02. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Please type a plus sign (+) inside this box → ☐

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number Of Pages In This Submission

13

Application Number

10/006,290

Filing Date

October 22, 2001

First Named Inventor

Jay WOHLGEMUTH, et al.

Group Art Unit

1645

Examiner Name

To Be Assigned

Attorney Docket No.

506612000100

ENCLOSURES (check all that apply)

☐ Fee Transmittal Form

☐ Fee Attached

☐ Amendment / Reply

☐ After Final

☐ Affidavits/declarations

☐ Extension of Time Request

☐ Express Abandonment Request

☒ SUPPLEMENTAL Information
Disclosure Statement - 3 pgs IN
DUPL

☐ PTO-1449 - 3 pgs IN DUPL with
[43] references attached

☐ Certified Copy of Priority Document(s)

☐ Response to Missing Parts/
Incomplete Application

☐ Response to Missing Parts
under 37 CFR 1.52 or 1.53

☐ Assignment Papers
(for an Application)

☐ Drawing(s)

☐ Licensing-related Papers

☐ Petition

☐ Petition to Convert to a
Provisional Application

☐ Power of Attorney, Revocation
Change of Correspondence Address

☐ Terminal Disclaimer

☐ Request for Refund

☐ CD, Number of CD(s) _____

☐ After Allowance Communication to
Group

☐ Appeal Communication to Board of
Appeals and Interferences

☐ Appeal Communication to Group
(Appeal Notice, Brief, Reply Brief)

☐ Proprietary Information

☐ Status Letter

☒ Other Enclosure(s) (please identify
below): **RETURN RECEIPT
POSTCARD**

RECEIVED

JUN 24 2002

TECH CENTER 1600/2900

SIGNATURE OF APPLICANT, ATTORNEY OR AGENT

Firm

Morrison & Foerster LLP

or

425 Market Street, San Francisco, CA 94105-2842

Individual Name

Michael R. Ward (Reg. No. 38,651)

Signature

Michael R. Ward

Date

June 4, 2002

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on June 4, 2002.

LILIA OLSEN



PATENT
Docket No. 506612000100

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:
Assistant Commissioner for Patents, Washington, D.C. 20231, on June 4, 2002.

LILIA OLSEN

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

J. WOHLGEMUTH, et al.

Serial No.: 10/006,290

Filing Date: October 22, 2001

For: LEUKOCYTE EXPRESSION
PROFILING

Examiner: To Be Assigned

Group Art Unit: 1645

RECEIVED
JUN 24 2002
TECH CENTER 1600/2900

SUPPLEMENTAL INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- ☒ **Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.**
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of * is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly, no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of * is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for

any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 506612000100. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: June 4, 2002

Respectfully submitted,

By: Michael R. Ward
Michael R. Ward
Registration No. 38,651

Morrison & Foerster LLP
425 Market Street
San Francisco, California 94105-2482
Telephone: (415) 268-6237
Facsimile: (415) 268-7522

Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 506612000100

Application Number 10/006,290

Applicant

J. Wohlgemuth et al.

Filing Date October 22, 2001

Group Art Unit 1645

Mailing Date June 4, 2002

RECEIVED

JUN 24 2002

TECH CENTER 1600/2900

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	05/18/1993	5,212,071	Fearon et al.			
	2.	11/23/1993	5,264,351	Harley			
	3.	08/23/1994	5,340,720	Stetler			
	4.	01/31/1995	5,385,824	Hoet et al.			
	5.	06/16/1998	5,766,585	Evans et al.			
	6.	11/09/1999	5,981,481	Fearon et al.			
	7.	01/04/2000	6,010,853	Kanteti et al.			
	8.	12/19/2000	6,162,604	Jacob			
	9.	01/23/2001	6,177,254 B1	Rattner et al.			
	10.	05/01/2001	6,225,093 B1	Grant et al.			
	11.	08/28/2001	6,280,941 B1	Tsao et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO

OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	12.	Bittner, M. et al. (2000) "Molecular classification of cutaneous malignant melanoma by gene expression profiling" <i>Nature</i> 406: 536-540.
	13.	Davas, E.M. et al. (1999) "Serum IL-6, TNFalpha, p55 srTNFalpha, p75srTNFalpha, srIL-2alpha levels and disease activity in systemic lupus erythematosus" <i>Clin Rheumatol</i> 18 (1):17-22.
	14.	Dugré, Francine J. (2000) "Cytokine and Cytotoxic Molecule Gene Expression Determined in Peripheral Blood Mononuclear Cells in the Diagnosis of Acute Renal Rejection" <i>Transplantation</i> 70 (7): 1074-1080.
	15.	Eisen, Michael B. et al. (1998) "Cluster analysis and display of genome-wide expression patterns" <i>Proc. Natl. Acad. Sci. USA</i> 95: 14863-14868.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

Docket Number 506612000100

Application Number 10/006,290

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

Applicant

J. Wohlgenuth et al.

RECEIVED

Filing Date October 22, 2001

Group Art Unit 1645

JUN 24 2002

Mailing Date June 4, 2002

TECH CENTER 1600/2900

- | | |
|-----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16. | Fu, Guoliang et al. (2002) "Representational difference analysis in a lupus-prone mouse strain results in the identification of an unstable region of the genome on chromosome 11" <i>Nucleic Acids Research</i> 30 (6): 1394-1400. |
| 17. | Gabay C. et al. (1997) "Circulating levels of tumor necrosis factor soluble receptors in systemic lupus erythematosus are significantly higher than in other rheumatic diseases and correlate with disease activity" <i>J Rheumatol</i> 24(2): 303-8. |
| 18. | Hastie, Trevor et al. (2001) "Supervised harvesting of expression trees" <i>Genome Biology</i> 2 (1): http://genomebiology.com/2001/2/1/research/0003 (4/25/02): 12 pages. |
| 19. | Hendricks, DA et al. (1995) "Quantitation of HBV DNA in human serum using a branched DNA (bDNA) signal amplification assay" <i>Am J Clin Pathol</i> 104 (5): 537-46. |
| 20. | Hsieh, Hsian-Guey et al. (2001) "IL-17 expression as a possible predictive parameter for subclinical renal allograft rejection" <i>Transpl Int</i> 14: 287-298. |
| 21. | Iida, K. et al. (1982) "Complement receptor (CR1) deficiency in erythrocytes from patients with systemic lupus erythematosus" <i>J. Exp. Med.</i> 155: 1427-1438. |
| 22. | Jagota, Arun (2000) <u>Data Analysis and Classification for Bioinformatics</u> . Bioinformatics By The Bay Press: 92-93. |
| 23. | Kasprzycka, Monika et al. (2002) "Expression of FasL gene in T cells of renal allograft recipients" <i>Immunol. Lett.</i> 80 (1): 9-13. |
| 24. | Katz, Mitchell H (1999) <u>Multivariable Analysis: A Practical Guide for Clinicians</u> . Cambridge University Press: 36-42. |
| 25. | Kobashigawa, J. et al. (1998) "A Randomized Active-Controlled Trial of Mycophenolate Mofetil in Heart Transplant Recipients" <i>Transplantation</i> 66 (4): 507-515. |
| 26. | Liossis, S.N. (2001) "B-cell kinase lyn deficiency in patients with systemic lupus erythematosus" <i>J Investig Med.</i> 49 (2): 157-65. |
| 27. | Melter, Michael et al. (2001) "Expression of the Chemokine Receptor CXCR3 and Its Ligand IP-10 During Human Cardiac Allograft Rejection" <i>Circulation</i> 104: 2558-2564. |
| 28. | Morita, Ken et al. (2001) "Early Chemokine Cascades in Murine Cardiac Grafts Regulate T Cell Recruitment and Progression of Acute Allograft Rejection" <i>J. Immunol.</i> 167: 2979-2984. |
| 29. | Nickel, Peter et al. (2001) "Cytotoxic Effector Molecule Gene Expression in Acute Renal Allograft Rejection" <i>Transplantation</i> 72 (6): 1158-1161. |
| 30. | Oh, Se-Il et al. (2001) "Correlation of Fas and Fas Ligand Expression with Rejection Status of Transplanted Heart in Human" <i>Transplantation</i> 71 (7): 906-909. |
| 31. | Rus, V et al. (2002) "Expression of cytokine- and chemokine-related genes in peripheral blood mononuclear cells from lupus patients by cDNA array" <i>Clin Immunol</i> 102 (3): 283-90. |
| 32. | Salmon, J. E. et al. (1996) "Fc-gamma-RIIA alleles are heritable risk factors for lupus nephritis in African Americans" <i>J. Clin. Invest.</i> 97: 1348-1354. |
| 33. | Shoker, Ahmed et al. (2000) "Heightened CD40 Ligand Gene Expression in Peripheral CD4+ Cells from Patients with Kidney Allograft Rejection" <i>Transplantation</i> 70 (3): 497-505. |

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 506612000100

Application Number 16/006 290

Applicant

J. Wohlgemuth et al.

Filing Date October 22, 2001

Group Art Unit 1645

Mailing Date June 4, 2002

JUN 24 2002

TECH CENTER 1600/2900



Shulzhenko, Natalia et al. (2001) "Monitoring of Intragraft and Peripheral Blood TIRC7 Expression as a Diagnostic Tool for Acute Cardiac Rejection in Humans" *Human Immunology* 62: 342-347.

35. Shulzhenko, Natalia et al. (2001) "Intragraft Activation of Genes Encoding Cytotoxic T Lymphocyte Effector Molecules Precedes the Histological Evidence of Rejection in Human Cardiac Transplantation" *Transplantation* 72 (10): 1705-1708.

36. Törönen, Petri et al. (1999) "Analysis of gene expression data using self-organizing maps" *FEBS Letters* 451: 142-146.

37. Tusher, Virginia Goss et al. (2001) "Significance analysis of microarrays applied to the ionizing radiation response" *PNAS* 98 (9) 5116-5121.

38. Vasconcellos, Lauro M. et al. "Cytotoxic Lymphocyte Gene Expression in Peripheral Blood Leukocytes Correlates with Rejecting Renal Allografts" *Transplantation* 66 (5): 562-566.

39. Vincenti, F. et al. (2001) "Multicenter Trial Exploring Calcineurin Inhibitors Avoidance in Renal Transplantation" *Transplantation* 71 (9): 1282-1287.

40. Watanabe-Fukunaga, R. et al. (1992) "Lymphoproliferation disorder in mice explained by defects in Fas antigen that mediates apoptosis" *Nature* 356: 314-317.

41. Whitehead, John. 2002. An Introduction to Logistic Regression.
(web page: <http://personal.ecu.edu/whiteheadj/data/logit/>). 4/25/02: 63 pages.

42. Wu, J. et al. (1996) "Fas ligand mutation in a patient with systemic lupus erythematosus and lymphoproliferative disease" *J. Clin. Invest.* 98: 1107-1113.

43. Zucker, S. et al. (1999) "Increased serum stromelysin-1 levels in systemic lupus erythematosus: lack of correlation with disease activity." *J Rheumatol.* 26 (1): 78-80.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.